SEP 2 3 2008

K081443

510(k) summary
MENICON Z (tisilfocon A) RIGID GAS PERMEABLE CONTACT LENSES
May 2008

1. Applicant Information

Menicon Co., Ltd.
21-19, Aoi 3-chome,
Naka-ku, Nagoya, Aichi 460-0006
JAPAN
Contact Person: Takahiro Ochi
Telephone No.: +81-52-937-5021
Fax No.: +81-52-935-1121
E-mail: t-ochi@menicon-net.co.jp

2. Device Information

Classification name: Lenses, Rigid Gas Permeable, Daily Wear Contact Lenses
Device classification: Class II
Regulation number: 21 CFR 886.5916
Product code: HQD
Proprietary name: Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses

3. Predicate Devices

Menicon claims substantial equivalence of the Menicon Z (tisilfocon A) to the following predicate devices.

- Rose K Post Graft Rigid Gas Permeable Contact Lenses: K013646
- Dyna Intra-Limbal lens (enflufocon A & hexafocon A): K020006
- Boston XO (hexafocon A), Boston EO (enflufocon B) and Boston ES (enflufocon A) Rigid Gas Permeable Contact Lenses: K013762, K053124, K071043.

4. Description of device

The Menicon Z lens material, tisilfocon A is a thermoset copolymer derived from fluoromethacrylate and siloxanylstyrene, bound by crosslinking agents.
The lens is tinted light blue with color additive D&C Green No. 6 (21 CFR 74.3206).
Also, UV absorber (benzotriazol) is added.

Lens designs for the management of irregular corneas include: 1) progressively flattening peripheral curves, 2) a reverse curve or series of reverse curves in the peripheral design, or 3) decentered optic zone and resulting peripheral curves, or 4) a combination of the first three systems.

5. **Indications for use**

The Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic or not-aphakic persons with non-diseased eyes.

The lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The lenses may be disinfected using a chemical disinfection system only.

6. **Description of safety and substantial equivalence**

The safety and efficacy of the Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens material was demonstrated in 510(k) Premarket Notifications and Premarket Approvals (PMA) as follows.

- K962006 cleared on October 9, 1996
- K970019 cleared on March 25, 1997 (multifocal designs)
- P990018 approved on July 11, 2000 (up to 7 days extended wear)
- P990018/S002 approved on July 12, 2002 (up to 30 days continuous wear)

Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to Rose K Post Graft Rigid Gas Permeable Contact Lenses, cleared in 510(k) Premarket Notification K013646 and Dyna Intra-Limbal lens Rigid Gas Permeable Contact Lenses, cleared in 510(k) Premarket Notification K020006, including an indication for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

7. **Clinical data:**

Clinical study for the Menicon Z (tisilfocon A) material has been deemed as not necessary in support of this clearance, as no new or additional questions of safety or effectiveness have been raised.

Results of a retrospective case study using the Menicon Z lenses for the management of keratoconus and other irregular corneal conditions demonstrated that the lenses effectively maintained corneal physiology and visual acuity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2008

Menicon Co. Ltd.
c/o Beverley D. Venuti, Ph.D., R.A.C.
Staff Consultant
Foresight Regulatory Strategies, Inc.
269A Ballardvale Street
Wilmington MA 01887

Re: K081443
Trade/Device Name: Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD
Dated: August 21, 2008
Received: August 25, 2008

Dear Dr. Venuti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081443

Device Name: Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lenses

Indications for Use:

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The lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The lenses may be disinfected using a chemical disinfection system only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
510(k) Number K081443